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applications having the serial numbers 09/478,855 and 09/227,912, both by R. Glenn et al., and both of which are incorporated herein.

## REMARKS

### Application Amendments

Claims 1-30 are pending in this application and all presently stand rejected. By the amendments presented, Claim 1 has been amended to more specifically define the present invention with incorporation of matter from Claim 7 and Claim 9. Claim 7, Claim 8 and Claim 9 have been deleted from the application. The Examiner has raised a rejection to Claim 18 with regard to insufficient antecedent basis for the limitation of phospholipids. Accordingly, Applicants have amended Claim 18 to be properly dependent on Claim 16 and not Claim 17. The Examiner has raised a rejection to Claim 19 with regard to insufficient antecedent basis for the limitation of quaternary ammonium halides and nonionic surfactants. Accordingly, Applicants have amended Claim 19 to be properly dependent on Claim 16 and not Claim 18. The specification at page 7 has been corrected to reflect the correct co-pending application No. 09/478,855. Applicants respectfully submit reconsideration of the 35 U.S.C. § 112 claim rejections based on the remarks above.

### Invention Synopsis

The present invention relates to a treatment composition, comprising an aqueous continuous phase; a reactive component comprising a reactive agent selected from the group consisting of either an electrophilic reactive group selected from the group consisting of halotriazine, haloquinoxaline, halopyrimidine, vinylsulfone,  $\beta$ -haloethylsulfone,  $\beta$ -sulfatoethylsulfone, acrylates, methacrylate, acrylamide, methacrylamide, maleimide, epoxide, acylhalide, ester, carbamate, dithiocarboxylic acid ester, alkoxysilane, thiosulfate, anhydride, urea derivative, isothiocyanate, isocyanate, lactone, thiosulfate, isothiuronium, azolactone electrophilic groups and mixtures thereof, or a protected thiol reactive group having the formula  $R-(S-Pr)_m$  where R is a mono or multivalent cosmetically active functional group, S is sulfur, Pr is a protecting group and m is an integer between 1 and 100; and b) a water immiscible solvent, wherein the water immiscible solvent solubilizes the reactive agent; and one or more surfactants wherein the surfactants emulsify the reactive component in the aqueous phase to form a bi-layer emulsion.

While not being bound to theory, it is believed that the water immiscible solvent comprising the reactive agent serves as a diffusion barrier that minimizes contact between the chemically unstable reactive agent and the aqueous phase. The structured bi-layers

surrounding the water immiscible solvent are a further barrier between the reactive agent and the aqueous phase. The bi-layers also serve to keep the reactive agent dispersed within the aqueous continuous phase over the shelf life of the composition to enable the delivery of the reactive agent to the hair in a consumer preferable medium.

### Art Rejections

#### 35 U.S.C. § 103(a)

a) Claims 1-6, 8 and 11-21 and 24-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zysman et al, U.S. 5,362,494, collectively "Zysman". The Examiner has asserted that it would have been obvious to one of ordinary skill in the cosmetic art by the teachings of Zysman to arrive at the present invention. Applicants respectfully traverse this rejection.

Zysman discloses nonionic amphiphilic compounds derived from glycerol containing several lipophilic chains (Col 1, lines 7-9) and their broad uses as dispersing agents, emulsifying agents or washing agents (Col 3, lines 38-41). Some of these glycerol compounds are capable of forming vesicles having a lamellar structure (Col 4, lines 33-40) which consist of a lipid phase consisting of one or more lamellae encapsulating a phase E (Col 4 lines 51-54). Moreover, other ionic amphiphilic lipids or nonionic amphiphilic lipids may be combined in the lipid phase with the glycerol compounds (Col 5 lines 23-26).

Zysman teaches the incorporation of an active agents within the lipid phase of the lamellae and/or in the phase encapsulated by the lamellae (col 7, lines 45-48). In the case of oil-in-water emulsions containing the glycerol compounds as emulsifying agents, the fat soluble compounds are entered into the oily phase and the water soluble compounds are entered into the aqueous phase (Col 7 lines 48-55). Zysman also teaches the inclusion of a dispersion of a water-immiscible liquid, which the vesicles physically stabilize which makes it unnecessary to utilize an ordinary emulsifier (Col 12, lines 19-24). Additionally, the water-immiscible liquid can contain one or more lipophilic active compounds (Col 12, lines 58-59). Numerous active compounds are claimed (see Table, columns 7-12) including thioglycolic acid, cysteamine, N-acetylcysteamine and glycerol thioglycolate (col 11, lines 63-69). Applicants have presently deleted Claim 8 of the present invention, covering a nucleophilic reactive groups.

Applicants would like to point out that Zysman teaches the 'basics' of the 'art' of bi-layer structures (in the context for use with the glycerol compounds), but this is not the novelty and unobvious invention that is in the present invention. The nucleophilic thiol compounds, as described in Zysman, are generally stable to hydrolysis and therefore are by far the easiest reactive compounds to stabilize within an aqueous medium. Indeed, one of

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skill in the art is familiar with the fact that they are already utilized within aqueous formulas today (w/o needing protection from a water immiscible solvent within a bi-layer emulsion) including commercially available permanent wave products -- the nucleophilic thiols inherent instability lies in their propensity to oxidize in the presence of atmospheric oxygen, but this can be solved via filling under nitrogen, airtight containers etc.

In contrast, in the present invention, the reactive electrophilic compounds of originally filed Claim 7 and the protected thiol reactive compounds of originally filed Claim 9 (possess an electrophilic protecting group), whose matter are now incorporated in Claim 1 of the present invention, are highly susceptible to hydrolysis and, therefore, must generally be formulated within an 'anhydrous' environment which is undesirable to the consumer. The present invention made the surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. Importantly, despite the 'general list' of agents listed in Zysman, none of them comprise known 'water-sensitive' electrophilic or protected thiol reactive groups as taught, and as now amended, required in the present invention.

Therefore, Zysman does not disclose nor make obvious the present invention, as now claimed.

b) Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Zysman et al, U.S. 5,362,494, as applied to Claims 1-6, 8 and 11-21 and 24-30 above, and further in view of Gough et al, U.S. 5,525,332, collectively "Gough".

As stated above, the matter of Claim 7 has now been incorporated into Claim 1 of the present invention.

Applicants would again like to point out that Zysman teaches the 'basics' of the 'art' of bi-layer structures (in the context for use with the glycerol compounds), but this is not the novelty and unobvious invention that is in the present invention. The nucleophilic thiol compounds, as described in Zysman, are generally stable to hydrolysis and therefore are by far the easiest reactive compounds to stabilize within an aqueous medium. Indeed, one of skill in the art is familiar with the fact that they are already utilized within aqueous formulas today (w/o needing protection from a water immiscible solvent within a bi-layer emulsion) including commercially available permanent wave products -- the nucleophilic thiols inherent instability lies in their propensity to oxidize in the presence of atmospheric oxygen, but this can be solved via filling under nitrogen, airtight containers etc.

In contrast, in the present invention, the reactive electrophilic compounds of originally filed Claim 7 and the protected thiol reactive compounds of originally filed

Claim 9 (possess an electrophilic protecting group), whose matter are now incorporated in Claim 1 of the present invention, are highly susceptible to hydrolysis and, therefore, must generally be formulated within an 'anhydrous' environment which is undesirable to the consumer. The present invention made the surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. Importantly, despite the 'general list' of agents listed in Zysman, none of them comprise known 'water-sensitive' electrophilic or protected thiol reactive groups as taught, and as now amended, required in the present invention. Therefore, Zysman does not disclose nor make obvious the present invention, as now claimed.

Furthermore, Gough does not teach the delivery of the electrophilic azalactone reactive group (w/in Claim 7) via inclusion within a water immiscible solvent that is then incorporated within a bilayer emulsion to achieve stability, as required by the present invention. Instead, Gough teaches the indiscriminate delivery of the azalactones in a number of plausible ways (most of them likely being judged by one of skill in the art to be chemically unstable for a commercial product, according to the present applicants) including water soluble or water/alcohol soluble azalactones delivered via aqueous or aqueous/alcoholic emulsions (Col 7 lines 49-55), organic soluble azalactones delivered via a mousse- or spray- type product, (Col 7 lines 60-65) or predissolving the azalactone in solvents for incorporation within a general cosmetic composition which may be aqueous or non-aqueous based (Col 8, lines 1-9). Applicant would kindly like to point out that that this is a different interpretation of this section than the Examiner, but Applicant believes this is highly accurate based on the wording used in Gough.

Hence, there is no teaching disclosing the delivery of 'water-sensitive' (See specification column 1, lines 31, column 2 lines 5-14) molecules (Claims 7 and 9) via the present invention for consumer preferred aqueous-based formula delivery and such would clearly not have been obvious to one of skill in the art from the Gough disclosure.

c) Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zysman et al, U.S. 5,362,494, as applied to Claims 1-6, 8 and 11-21 and 24-30 above, and further in view of Deppert et al, U.S. 5,525,332, collectively "Deppert".

The Examiner asserts that Zysman fails to teach the claimed reactive compounds containing a nucleophilic reactive group, in particular, thiol groups. However, the Examiner continues by asserting that Zysman suggests incorporating hair-conditioning agents in the aqueous dispersions containing amphiphilic vesicles. Therefore, the Examiner asserts that it would have been obvious for one of an ordinary skill in the art to

incorporate the sulfur containing quaternary ammonium compound such as disulhydryl, dithiol or diisothiouranium containing quaternary ammonium conditioners of Deppert in the aqueous dispersions containing amphiphilic vesicles of Zysman.

Applicants would again like to point out that Zysman teaches the 'basics' of the 'art' of bi-layer structures (in the context for use with the glycerol compounds), but this is not the novelty and unobvious invention that is in the present invention. The nucleophilic thiol compounds, as described in Zysman, are generally stable to hydrolysis and therefore are by far the easiest reactive compounds to stabilize within an aqueous medium. Indeed, one of skill in the art is familiar with the fact that they are already utilized within aqueous formulas today (w/o needing protection from a water immiscible solvent within a bi-layer emulsion) including commercially available permanent wave products -- the nucleophilic thiols inherent instability lies in their propensity to oxidize in the presence of atmospheric oxygen, but this can be solved via filling under nitrogen, airtight containers etc.

In contrast, in the present invention, the reactive electrophilic compounds of originally filed Claim 7 and the protected thiol reactive compounds of originally filed Claim 9 (possess an electrophilic protecting group), whose matter are now incorporated in Claim 1 of the present invention, are highly susceptible to hydrolysis and, therefore, must generally be formulated within an 'anhydrous' environment which is undesirable to the consumer. The present invention made the surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. Importantly, despite the 'general list' of agents listed in Zysman, none of them comprise known 'water-sensitive' electrophilic or protected thiol reactive groups as taught, and as now amended, required in the present invention. Therefore, Zysman does not disclose nor make obvious the present invention, as now claimed.

Deppert discloses processes for conditioning human hair by treatment with selected sulfur containing quaternary ammonium compounds, compositions useful for such processes and novel quaternary compounds useful for the proccsses. Deppert, while disclosing the use of selected sulfur containing quaternary ammonium compounds, is also silent with regard to the use of selected surfactants and water immiscible solvents to form structured bilayers. Further, as now claimed, there would be no motivation to combine the teachings of Deppert with Zysman, and arrive at the present invention, as both references are silent with regard to the present invention surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a

structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. In column 10, lines 44-49, Deppert mentions very briefly a list of common formulation excipients including coloring agents, fragrances, surfactants, buffers etc., and emulsifying agents. However, in Deppert, there is no mention of structured bi-layers as taught & required in the present invention. Deppert neither discloses or makes obvious the need for the described sulfur containing quaternary ammonium salts to be formulated within an 'anhydrous' environment which is undesirable to the consumer. Deppert neither discloses nor makes obvious that such sulfur containing quaternary ammonium salts need or would benefit if they were to be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. This is the surprisingly discover of the present invention. Therefore, one of skill in the art would not be motivated to combine the teaching of Zysman and Deppert in order to arrive at the present invention, in that neither of these reference, either alone or combination, disclose the present invention's surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. Zysman is not directed toward the present invention, as detailed above, and Deppert is even further removed from teaching or suggesting a need to combine the described compounds in Deppert with the teachings of Zysman. Therefore one of skill in the art would not be motivated to combine Zysman with Deppert and arrive at the present invention.

Further, one of ordinary skill in the art would not have been lead or motivated to modify the compositions of Zysman by adding or blending the teachings of Deppert and successfully arrive at the present invention.

### **No Prima Facie Case**

Applicant respectfully traverses this obvious rejection, as Zysman and Gough and Deppert do not establish a prima facie case of obviousness because they do not teach or suggest all of the Applicant's claim limitations. None of the references, either alone or in combination, teach the specific composition as required by the present invention. Namely, none of the references, either alone or in combination, teach or suggest a treatment composition, comprising an aqueous continuous phase; a reactive component comprising a reactive agent selected from the group consisting of either an electrophilic reactive group

selected from the group consisting of halotriazine, haloquinoxaline, halopyrimidine, vinylsulfone,  $\beta$ -haloethylsulfone,  $\beta$ -sulfatoethylsulfone, acrylates, methacrylate, acrylamide, methacrylamide, maleimide, epoxide, acylhalide, ester, carbamate, dithiocarboxylic acid ester, alkoxysilane, thiosulfate, anhydride, urea derivative, isothiocyanate, isocyanate, lactone, thiosulfate, isothiuronium, azolactone electrophilic groups and mixtures thereof, or a protected thiol reactive group having the formula  $R-(S-Pr)_m$  where R is a mono or multivalent cosmetically active functional group, S is sulfur, Pr is a protecting group and m is an integer between 1 and 100; and b) a water immiscible solvent, wherein the water immiscible solvent solubilizes the reactive agent; and one or more surfactants wherein the surfactants emulsify the reactive component in the aqueous phase to form a bi-layer emulsion.

Therefore, there is no prima face case of obviousness since none of the references, either alone or when combined, teach or suggest all of the Applicant's claim limitations.


In light of the arguments presented herein, it is respectfully submitted that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

### Conclusions

Applicants have made an earnest effort to place their application in proper form and distinguish their claimed invention from the references which were applied in the July 12, 2002 Office Action. WHEREFORE, consideration of this application, withdrawal of the rejections under 35 U.S.C § 112 and 103, and allowance of the pending Claims are respectfully requested.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

1. (AMENDED) A treatment composition, comprising:
- i) an aqueous continuous phase;
  - ii) a reactive component comprising: a) a reactive agent selected from the group consisting of either an electrophilic reactive group selected from the group consisting of halotriazine, haloquinoxaline, halopyrimidine, vinylsulfone,  $\beta$ -haloethylsulfone,  $\beta$ -sulfatoethylsulfone, acrylates, methacrylate, acrylamide, methacrylamide, maleimide, epoxide, acylhalide, ester, carbamate, dithiocarboxylic acid ester, alkoxysilane, thiosulfate, anhydride, urea derivative, isothiocyanate, isocyanate, lactone, thiosulfate, isothiuronium, azolactone electrophilic groups and mixtures thereof, or a protected thiol reactive group having the formula



- where R is a mono or multivalent cosmetically active functional group, S is sulfur, Pr is a protecting group and m is an integer between 1 and 100; and b) a water immiscible solvent, wherein the water immiscible solvent solubilizes the reactive agent; and b) a water immiscible solvent, wherein the water immiscible solvent solubilizes the reactive agent; and
- iii) one or more surfactants wherein the surfactants emulsify the reactive component in the aqueous phase to form a bi-layer emulsion.

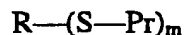
18. (AMENDED) A treatment composition according to Claim 16[17], wherein the surfactant from about 1% to about 20% of phospholipids.
19. (AMENDED) A treatment composition according to Claim 16[18], wherein the surfactant comprises from about 1% to about 10% of a quaternary ammonium halide, and from about 1% to about 20% of a nonionic surfactant.



**VERSION WITH MARKINGS TO SHOW CHANGES MADE****IN THE SPECIFICATON:**

At page 7, lines 20-29, please replace with the following paragraph:

Protected Thiol reactive groups or "hooks" that may be included within reactive agents of the present inventions include, but are not limited to, reactive groups of the following structure:



where R is a mono or multivalent cosmetically active functional group, S is sulfur, Pr is a protecting group and m is an integer between 1 and 100. The protecting group is selected from the group consisting of heterocyclic protecting groups,  $sp^2$  aliphatic trigonal carbon protecting groups,  $sp^3$  carbon electrophilic protecting groups, phosphorus protecting groups, metal based protecting groups, non-metal and metalloid based protecting groups, energy-sensitive protecting groups and mixtures thereof as described in U.S. patent applications having the serial numbers 09/478,8[66]55 and 09/227,912, both by R. Glenn et al., and both of which are incorporated herein.